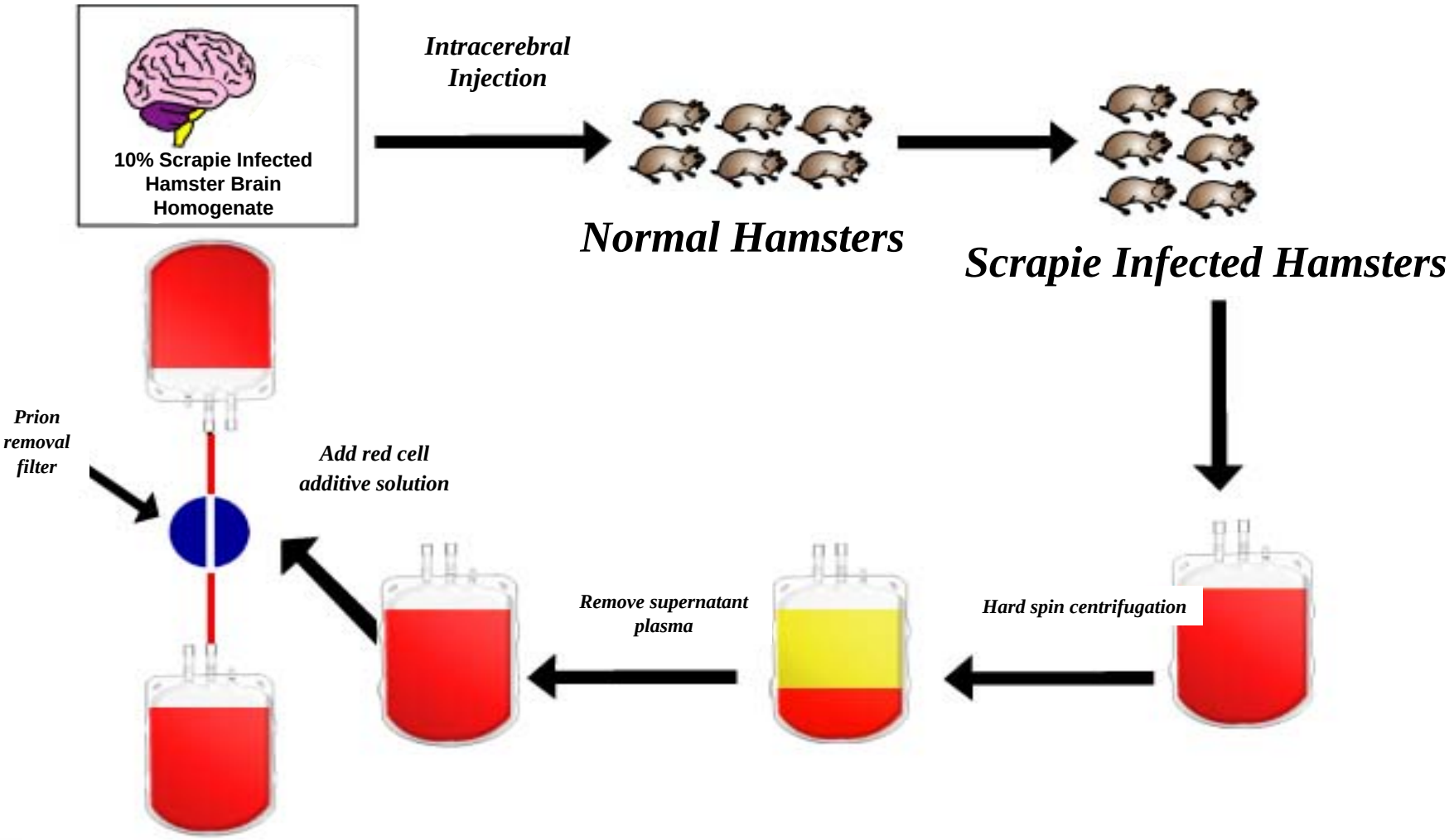
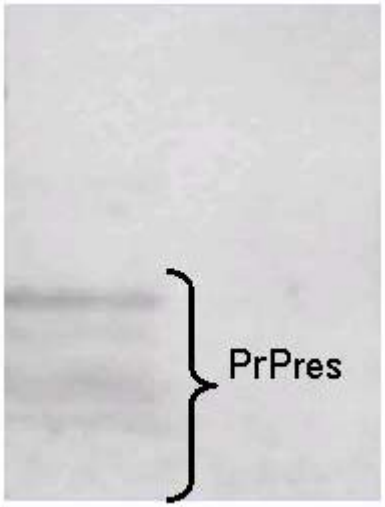
Additional Studies: Endogenous Study Western Blot



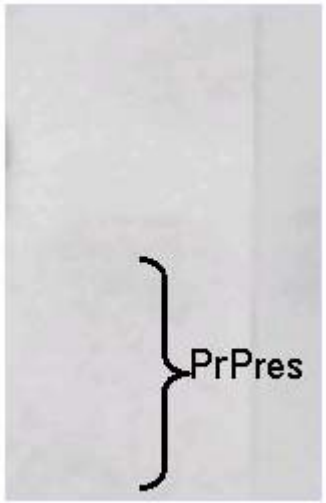
Additional Studies: Endogenous Study Western Blot

Western Blots After Proteinase K Digestion



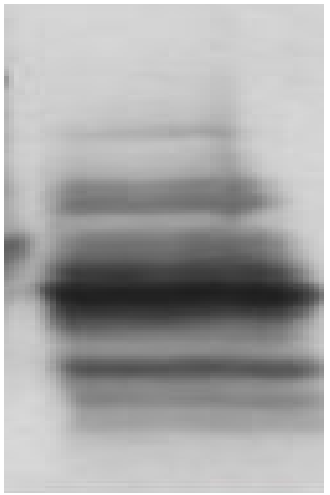
Before Filtration

Barely detectable



After Filtration

Not detectable



Recovered from Filter and Concentrated 500x

A lot of recoverable prion

Product Safety Studies

Test	Purpose	Result
Hemolysis – Rabbit – Blood*	Red Cell Integrity	PASS
MEM Elution Cytotoxicity*	Absence of toxic effect on cells	PASS
Physicochemical Test for Plastics*	Absence of negative biochemical effects on cells	PASS
Intracutaneous Injection Test*	Absence of irritant	PASS
Kligman Maximization Test*	Absence of allergens	PASS
Systemic Injection Test – ISO*	Absence of toxic effect on cells	PASS
Oxygen/Hemoglobin Affinity*	No effect on oxygen carrying capability	PASS
Immunohematology	RBC antigen expression, IgG level, complement coating	PASS

* ISO 10993-1 #USP

Summary

- In prototype filters, SIHBH prion levels were reduced by 3.7 log in a bioassay when Western blot data showed >2 log
- Final filter design Western blot 2.9±0.7 log reduction (N=48), bioassay and infectivity study currently underway
- Quality of the blood cells is unaffected by prion reduction filtration
- Safety studies showed no causes for concern
- 24-hr single and double isotope red cell survival unaffected by filtration
- Residual white blood cells further reduced by filtration to levels $<1x10^5$ (98% of the time, 95% confidence) significantly lower than the current standard for leukoreduced blood